

### **REMARKS**

Claim 26 is amended to more clearly characterize the coating composition. Support for this amendment can be found in the specification at, for example, pg. 9, lns. 6-17. New claim 41 is supported in the specification at, for example, pg. 9, ln. 2. New claims 42 and 43 are supported in the specification at, for example, pg. 9, lns. 6-17. With entry of these amendments, claims 26, 36, 37, and 41-43 will be pending in this application.

### **REJECTIONS UNDER § 112**

Claims 26, 36, and 37 were rejected under § 112, second paragraph, as being indefinite. In view of the Examiner's comments, and in order to expedite prosecution of this application, claim 26 is amended to more clearly define the invention and satisfy the requirements of § 112, second paragraph. Accordingly, favorable consideration and withdrawal of this rejection are respectfully requested.

### **REJECTIONS UNDER § 102**

Claims 26, 36, and 37 were rejected under § 102(b) as being anticipated by U.S. Patent No. 4,994,167 (Shults et al.). Applicant respectfully requests reconsideration of this rejection.

Claim 26 recites a composition in which the polyfunctional cross-linking agent contains "cross-linking functional groups [that] are present in an amount sufficient to cross-link at least some of the organic acid functional groups [on the polycarbonate-polyurethane] and provide unreacted cross-linking functional groups that can react with a bio-active agent." By having unreacted functional groups on the cross-linking agent, the cross-linking agent can then be reacted with a bioactive agent.<sup>1</sup>

Unlike the invention of claim 26, *Shults* has no disclosure of a cross-linking agent having the above-mentioned features. *Shults* refers to BAYBOND 123, which is described as being a "polycarbonate urethane polymer."<sup>2</sup> *Shults* also states: "[t]he polyurethane polymer is crosslinked in the presence of the polyvinylpyrrolidone by preparing a premix of the polymers and adding a cross-linking agent just prior to the production of the membrane."<sup>3</sup> However, there

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<sup>1</sup> Specification, pg. 9, lns. 15-17.

<sup>2</sup> *Shults*, col. 13, lns. 28-30.

<sup>3</sup> *Shults*, col. 13, lns. 52-55.

is no disclosure or even a suggestion that any of the functional groups on the cross-linking agent used in *Shults* are left unreacted, as required by claim 26.

For at least these reasons, Applicant respectfully submits that *Shults* does not anticipate claims 26, 36, and 37. Accordingly, favorable consideration and withdrawal of this rejection are respectfully requested.

### REJECTIONS UNDER § 103

Claims 26, 36, and 37 were rejected under § 103(a) as being rendered obvious by *Shults* in view of U.S. Patent No. 4,888,285 (Nishimura et al.) or No. 4,287,305 (Compere et al.) or No. 4,979,959 (Guire). Applicant respectfully requests reconsideration of this rejection.

Without conceding that the suggested combination of *Shults* with *Nishimura* or *Compere* or *Guire* is proper, Applicant respectfully submits that these combinations cannot meet the invention of claim 26, which recites a composition in which the polyfunctional cross-linking agent contains “cross-linking functional groups [that] are present in an amount sufficient to cross-link at least some of the organic acid functional groups [on the polycarbonate-polyurethane] and provide unreacted cross-linking functional groups that can react with a bio-active agent.”

As explained above, *Shults* does not disclose a cross-linking agent having this feature. Furthermore, neither *Nishimura* or *Compere* or *Guire* explicitly discloses a cross-linking agent having this feature, and thus, does not add anything that would remedy the deficiencies of *Shults*. As such, the combination of *Shults* with *Nishimura* or *Compere* or *Guire* fails to have all the required elements of claim 26. For at least these reasons, Applicant submits that claims 26, 36 and 37 are non-obvious over *Shults* in view of *Nishimura* or *Compere* or *Guire*.

Furthermore, Applicant submits that although *Shults* discloses a cross-linked polycarbonate-urethane polymer, there is no reason to cross-link the polycarbonate-urethane polymers in such a way that unreacted cross-linking functional groups are provided, as required by the claimed inventions. The cross-linking agent in the composition of claim 26 serves at least two purposes.<sup>4</sup> The first purpose is to cross-link the polycarbonate-polyurethane polymers. The second purpose is to provide unreacted functional groups that are available to optionally bond with a bio-active agent. These two functions are explicitly recited in claim 26.

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<sup>4</sup> Specification, pg. 9, lns. 5-17.

In contrast, *Shults* describes a biological fluid measuring device for determining the presence and amounts of substances in a biological fluid.<sup>5</sup> One of the components of the *Shults* device is a membrane which acts as a barrier to prevent “direct contact of the fluid sample with the electrodes” while permitting “selected substances of the fluid to pass through the membrane for electrochemical reaction with the electrodes.”<sup>6</sup> This membrane can be formed from polyurethane polymers which are cross-linked using a cross-linking agent.<sup>7</sup> Thus, *Shults* only requires cross-linking of the polyurethane polymers so that the membrane can function as an effective barrier, and as such, there is no reason to provide unreacted cross-linking functional groups in the cross-linking agent of *Shults*. Indeed, *Shults* discloses that the cross-linking agent is present in an amount of about 5 wt% and the polymer in an amount of about 70-91 wt%.<sup>8</sup> With such a large amount of polymer relative to the cross-linking agent, unreacted cross-linking functional groups would not be expected.

For at least these reasons, Applicant submits that claims 26, 36, and 37 are non-obvious over *Shults* in view of *Nishimura* or *Compere* or *Guire*. Accordingly, favorable consideration and withdrawal of this rejection are respectfully requested.

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<sup>5</sup> *Shults*, Abstract.

<sup>6</sup> *Shults*, col. 4, lns. 54-58.

<sup>7</sup> *Shults*, col. 13, lns. 5-10.

<sup>8</sup> *Shults*, col. 14, lns. 4-8.

**CONCLUSION**

Applicant respectfully submits that the present application is in condition for allowance. The Examiner is invited to contact Applicant's representative to discuss any issue that would expedite allowance of this application.

The Commissioner is authorized to charge all required fees, fees under § 1.17, or all required extension of time fees, or to credit any overpayment to Deposit Account No. 11-0600 (Kenyon & Kenyon LLP).

Respectfully submitted,

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